K031322

DEC 2 3 2003

510(k) Summary

Pursuant to 512(i)(3)(A) of the Food, Drug and Cosmetic Act, Intra-Lock International is required to submit with this Premarket Notification either an "...adequate summary of any information respecting safety and effectiveness or state that information will be made available upon request of any person." Intra-Lock International chooses to submit a summary of the safety and effectiveness information. The summary is as follows:

Trade Name: **Intra-Lock Hydroxyapatite Coated Implants**

Sponsor: Intra-Lock International
1200 North Federal Highway, Suite 200
Boca Raton, FL 33432
Registration No.:3003631996

Device Generic Name: **HA Coated Dental Implants**

Classification: According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class III.

Predicate Devices:

Ace HA Screw Implant System	**K021244**
HA-TI Implant	**K003045**
BMR Dental Implant System	**K010343**
Replace Ha Coated Implants	**K962845**
Sterngold HA Coated Screws	**K981516**
Restore HA Coated Implants	**K960288**

Product Description:

The Intra-Lock Hydroxyapatite Coated Implants consists of root form dental implants that are manufactured from CP Ti and have a Hydroxyapatite coating. These implant designs are either threaded or smooth cylindrical shapes and are substantially equivalent to devices previously marketed. They have the same indications and applications for surgical restoration of partially or fully edentulous patients as pre-amendment devices.

Indications for Use:

The Intra-Lock Hydroxyapatite Coated Implants have been designed to restore partially or fully edentulous patients. The implants have been designed to be used in either the mandible or maxilla and to support removable or fixed prosthesis, from single tooth replacement to full arch reconstruction.

Safety and Performance:

This submission is a Special 510(k): Abbreviated 510(k) as described in FDA's guidance document entitled "The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications." In support of this 510(k), Intra-Lock International has provided information to demonstrate conformity with FDA's guidance document entitled: Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Abutments Draft Guidance for Industry and FDA.

Conclusion:

Based on the indications for use, technological characteristics, and comparison to predicate devices, the Intra-Lock Hydroxyapatite Coated Implants have been shown to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 3 2003

Mr. Jeffrey Sakoff
Vice Present & Director of Operations
Intra-Lock International
1200 N. Federal Highway, Suit #200
Boca Raton, Florida 33432

Re: K031322
Trade/Device Name: Intra-Lock Hydroxyapatite Coated Dental Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: III
Product Code: DZE
Dated: September 29, 2003
Received: September 30, 2003

Dear Mr. Sakoff:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Kei Mulay

for Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K031322

Device Name: Intra-Lock Hydroxyapatite Coated Dental Implants

Indications for Use:

The Intra-Lock Hydroxyapatite Coated Implants have been designed to restore partially or fully edentulous patients. The implants have been designed to be used in either the mandible or maxilla and to support removable or fixed prosthesis, from single tooth replacement to full arch reconstruction.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the -Counter Use ____
(Per 21 CFR 801.109)

for MSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K031322